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Serial No: 09/978,464

**REMARKS/ARGUMENTS**

Consideration of the amendments presented herein and reconsideration of certain grounds for rejection are respectfully requested. In the present amendments, claims 25 and 27 are cancelled without prejudice. Upon entry of the present amendments, claims 1-24, 26, 28, and 31-34 are pending in the application.

**Claim Rejections - Double Patenting**

The Examiner has rejected claims 1-28 and 31-34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,379,943.

Applicant provides herein a Terminal Disclaimer with Statement under 37 CFR 3.73.(b), copy of relevant assignment, and appropriate fee to overcome this rejection for the claims pending in this application. Entry of this Terminal Disclaimer in this case is respectfully requested.

**Claim Rejections - 35 USC 112, first paragraph**

Claims 7, 9, 14, 17, 18, 24, 25, 28, 30 and 31 stand rejected under 35 USC 112, first paragraph, as failing to comply with the enablement requirement. To advance this application to issue, and to better claim the subject matter that Applicant regards as his invention, Applicant has amended claims 7, 9, 14, 17, 18, 24, 28, 30 and 31, and has cancelled claim 25, to overcome this rejection. Applicant also believes that claim 11 was inadvertently omitted from this listing, and also has amended this claim accordingly.

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The Examiner in the April 20, 2004 Final Office action acknowledged Applicant's previous statement that "some precursor plasmids are currently available commercially," inferentially concluded that some plasmids are not commercially available, and stated a requirement for a deposit of plasmids. Applicant notes that the MPEP states that "Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement [of being known and readily available]" MPEP 2404.01. It is noted that no basis was provided with the Examiner's statement that their commercial source may become unavailable. The MPEP also states that Applicant may show that a deposit is not necessary when biological materials "can be made or isolated without undue experimentation" (MPEP 2404.02).

Accordingly, the Applicant maintains that no deposit is required for the species remaining after amendment in the above-noted claims. These are, or constructed from, plasmids that are commercially available. In the latter case, these are constructed from a commercially available plasmid as taught in the specification, thereby not requiring undue experimentation (i.e., based on combination of the above two excerpts from the MPEP).

The above rules and argument apply specifically to the following plasmids which are retained in the dependent claims, the commercial source and/or modification of which are provided as follows:

For Claim 7 (and other subsequent dependent claims listing these species) pBHGlox $\Delta$ E1,3, pBHG11lox, pBHGE3lox are all derived from pBHG10, pBHG11, and pBHGE3 which are available from Microbix. Their derivation is described in Figs 4A and 4C and example 4, page 43 line 21 to page 44 lines 1-12.

pBHGlox $\Delta$ E1,3Cre is available from Microbix as part of Kit D.

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pFG173lox is derived from pFG173 (Microbix), pCA14 (Microbix) and pAB14lox as described in Figures 9B,C page 56 lines 18-22 and page 57 lines 1-13. pAB14lox is itself derived from pAB14 (Microbix) as described in Figure 14, page 61, lines 5-7.

In Claim 9 (and other subsequent dependent claims listing these species), p $\Delta$ E1sp1Alox, p $\Delta$ E1sp1Alox $\Delta$ , p $\Delta$ E1sp1Blox, and p $\Delta$ E1sp1Blox $\Delta$  are all derived from p $\Delta$ E1sp1A (Microbix) and p $\Delta$ E1sp1B (Microbix) as described in Fig. 5A and page 45, lines 18-22 and page 46, lines 1-4.

Also, pCA13lox, pCA13lox $\Delta$ , pCA14lox, and pCA14lox $\Delta$  are derived from pCA13 and pCA14 as described in Figures 7 and 8A and page 47, lines 6-20. Both pCA13 and pCA14 are available from Microbix.

Further, in view of the clear instructions in the specification, and the high level of skill in the art with regard to modification of DNA material by use of restriction endonucleases, the noted dependent claims regarding specific examples of the second nucleic acid have been amended to clearly indicate that the remaining listed plasmids are precursors to the final second nucleic acids used in the respective method, system, kit or vector claim. That is, in view of the level of skill in the art, the specification teaches that various species may be constructed in similar manner to the particular species that are shown constructed by modification of one or more of the plasmids specified in the claims. For example, several disclosures of methods of construction by modification begins in the specification on page 43, line 21, and continues to page 44, line 12, page 45, line 18 to page 46, line 4, and page 12, lines 4-13. These examples, in view of the high level of skill in the art, are sufficient to enable design and construction of a number of possible species without undue experimentation. A reason for this approach is that this approach effectively overcomes the lack of a head-to-head ITR junction in commercially available precursor plasmids which remain in the claims (see next section), while properly further limiting the scope of the claims upon which these claims depend.

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Based on the above amendments and argument, reconsideration and withdrawal of the stated ground(s) of rejection are respectfully requested. Also, no new matter has been added by the above amendments.

**Claim Rejections - 35 USC 112, second paragraph**

Claims 9, 11, 14 and 18 stand rejected under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. The stated specific basis for this rejection is that "at least some of the recited plasmids do not appear to have a head-to-head ITR junction, which is a requirement recited in the claim on which the rejected claims depend . . .". (Page 5 of Final Office action) Applicant also believes that claims 25, 28 and 31 were inadvertently omitted from this listing.

To advance this application to issue, and to better claim the subject matter that Applicant regards as his invention, Applicant has amended claims 9, 11, 14, 18, 28 and 31, and has cancelled claim 25, to overcome this rejection. With regard specifically to claim 11, part (i) of the claim was eliminated as with the claim as amended the elements in part (i) are either irrelevant or redundant (i.e., as to redundant, the requirement for a head-to-head ITR junction already is in claim 10, part (b), and need not be repeated in dependent claim 11). With regard specifically to claim 31, since this claim is independent and the presence of a head-to-head ITR junction in the second vector was not otherwise established for the claim as amended, the phrase "and comprising a head-to-head ITR junction" is added. For the other amended claim as to this basis for rejection, the presence of a head-to-head ITR junction is established in claims upon which these amended claims depend.

As noted in the preceding section, the claims as amended list commercially available precursor plasmids that lack a head-to-head ITR junction, and which, however, are readily and without undue experimentation modifiable to second nucleic acid constructs that comprise a head-to-head

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ITR junction. Thus, the present amendments to these claims overcome the stated basis for rejection by eliminating the issue of whether a particular named final species (i.e., a plasmid species that possesses all characteristics for a second nucleic acid) comprises a head-to-head ITR junction. At a minimum, this is because only precursors are specified, the claim limitations (whether in the claim at issue or one from which it depends) clearly indicate that the final plasmid comprises a head-to-head ITR junction (as well as other limitations), the teachings to insert such head-to-head ITR junction are clearly exemplified, and a number of commercially available plasmids provide an appropriate nucleic acid sequence fragment that comprises a suitable head-to-head ITR junction.

As to the latter, it is noted that although pCA35loxITR (see Figure 5B, and page 12, lines 4-13), shown as a source of a PvuI-XbaI fragment containing the ITR, is not commercially available, many similar plasmids that contain the same fragment are commercially available. In particular, a number of the AdMax plasmids sold by Microbix contain this same PvuI-XbaI fragment and could be just as easily used in place of pCA35loxITR. Among others, for example, pDC311-316 in KitD, DC511-516 in KitE, DC411 in KitF comprise this PvuI-XbaI fragment, are commercially available, and are readily combined with currently listed precursors to obtain suitable second nucleic acid plasmids. These commercially available plasmids can be substituted in place of pCA35loxITR as shown in Figure 5B to obtain second nucleic acid plasmids in the same way as described in the specification corresponding to Figure 5B, page 12, lines 4-13. In addition to this fragment being available in such complete, commercially available plasmids, plasmid sequences comprising this PvuI-XbaI fragment also are available from Microbix.

Thus, the claims as amended are not indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. Also, no new matter has been added by the above amendments.

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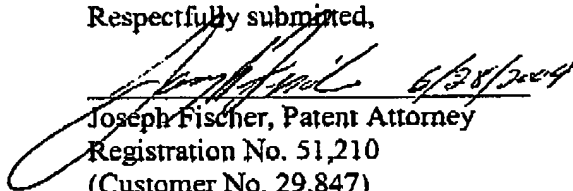
Based on the above amendments and argument, reconsideration and withdrawal of the stated ground(s) of rejection are respectfully requested.

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All claims having either been placed in condition for allowance or cancelled, expedited passage of this case to issuance is respectfully solicited.

If certain terms or clauses remain in the claims as amended which the Examiner finds still present a rejection under 35 USC 112, or if the Examiner believes that any valid basis of non-patentability remains after consideration of the amendments and the remarks herein, the courtesy of a telephone call to the Attorney for Applicant will be most appreciated, in order to provide an opportunity to reach mutually agreeable resolution, including finding acceptable claim language in view of the claim types, the specification, and the knowledge in the field, and/or cancellation of claim that the Examiner maintains are not allowable.

Respectfully submitted,



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